

Valencia Branch Laboratory Update

February 22, 2021

Q: Are you going to close the laboratory due to the Laboratory Field Services (LFS) inspection report?

A: PerkinElmer is confident these deficiencies will be quickly remedied to avoid any impact on the laboratory's license. The laboratory has not waited to address these issues, but instead has worked to make numerous improvements since the onsite inspection.

Q: What specific deficiencies did LFS cite?

A: The deficiencies are focused in five areas, including: facility administration, pre-analytical process, analytical systems, post-analytical process, and laboratory leadership.

Q: When will the final report be made available publically from LFS?

A: The report will be made available mid-March once PerkinElmer has had a chance to respond to the deficiencies and LFS has had the opportunity to review the responses.

Q: Does the immediate jeopardy designation mean that LFS will revoke the license?

A: PerkinElmer is confident these deficiencies will be quickly remedied to avoid any impact on the laboratory's license. The laboratory has until March 1 to provide LFS with appropriate documentation with how it has addressed or plans to address the laboratory's initial challenges. If the material provided is satisfactory to LFS the immediate jeopardy does not apply.

Q: What is CAP accreditation?

A: The College of American Pathologists or CAP has an independent, third-party accreditation program for laboratories. So that Californians have no doubt about the quality of the services at the laboratory, PerkinElmer is seeking CAP accreditation. The Valencia Branch Laboratory had its initial accreditation inspection on Friday, February 19, 2021 and PerkinElmer fully expects a prompt and positive response.

Q: When did the LFS inspection citing the deficiencies occur?

A: The inspection occurred on December 8-9, 2020. Since then, LFS has been preparing a written report. LFS had an exit conference with laboratory leadership on Wednesday, February 17, 2021, and provided them with the written report to respond to on Friday, February 19, 2021.

Q: Is this different from the investigation related to the recent employee allegations reported?

A: Yes. This is an LFS regulatory inspection of the laboratory. This onsite inspection occurred December 8-9, 2020. The complaint investigation related to recent employee allegations is different and that investigation is ongoing.

Q: When will the complaint investigation related to the employee allegations be complete?

A: We do not have a timeline for when the investigation will be completed. We need to let the laboratory experts do their work and see if complaints are substantiated.

Q: Do you have any knowledge or evidence that PerkinElmer has instructed staff to destroy evidence?

A: No. We have asked for any evidence of alleged document tampering and have been declined. Such actions, if true, are completely unacceptable and are against the law. It would go against our values and standards, and we hold all our vendors to the same values and standards.

Q: What actions can you take against PerkinElmer?

A: We included strong contractual language to ensure that we protected the state and the taxpayer dollar. The full contract is public and can be found online on the covid19.ca.gov website, [here](#).

Q: Would you terminate this contract if the reported employee allegations are substantiated?

A: We need to let the laboratory experts do their work and see if complaints are substantiated -- and then the state will take any action that may be merited.

Q: Has PerkinElmer cooperated with the team deployed investigating the complaint?

A: Yes.

Q: Do you have confidence in PerkinElmer to deliver on the contract?

A: Yes. There is currently nothing to suggest that we do not have confidence in their ability to deliver on the contract. Obviously, we are constantly assessing their performance and are ensuring that they are delivering the best results for the people of California.

Q: Why is the state not resulting Ct values 37-42 as positive pursuant to the FDA EUA?

A: Out of an abundance of caution, and to be more conservative, the laboratory is resulting Ct values up to 37 as positive, Ct values 37 to 42 as presumptive positive, and Ct values above 42 as negative. These thresholds and interpretations were developed and validated based on characteristics of the patient population and testing sites. In terms of resulting and the cutoffs, the laboratory has made changes only to the result thresholds and interpretation under the authority of a Laboratory Developed Test or LDT.

Q: Is PerkinElmer in violation of the contract for using a Laboratory Developed Test (LDT)?

A: PerkinElmer's use of the Laboratory Developed Test is consistent with its contract. The Scope of Work, on page 8 under Exhibit A of the contract, allows for changes to technology and methodology. The full contract is public and can be found online on the covid19.ca.gov website, [here](#).

Q: Why did the state not go through a competitive contract process?

A: PerkinElmer was unique as they control the entirety of the supply chain meaning that they not only build their own laboratory machines, they also produce all the necessary reagents and testing kits. We have not found any company that controls the supply chain to this extent. The company also has a long-standing track record with California's genetic disease screening program for the state. Additionally, to mitigate the fiscal exposure and overall risk to the state, we have included a number of provisions in the contract, including change in technology

provision, termination provision, test reliability provision, test turnaround provision, and the claw back provision.

Q: Doesn't California have a lot of testing capacity now? What makes this lab different?

A: Earlier in the pandemic, there were testing deserts in some of the areas hardest hit by COVID-19. The Valencia Branch Laboratory successfully increased testing availability in communities at high risk for contracting COVID-19 such as essential workers, those in congregate care settings, and communities of color. The Valencia Branch Laboratory has performed more than 1.5 million tests on samples from a network of more than 1,500 specimen collection sites developed with churches, schools, clinics, essential workplaces, and community-based organizations.

Q: Why is the volume in the laboratory declining?

A: This is not unique to the Valencia Branch Laboratory, it is happening in laboratories across the state, and across the country. Moreover, we currently have over 1,500 test sites approved and on-boarded with the Valencia Branch Laboratory with a forecasted test volume of 502,000 tests per week, which equates to roughly 72,000 tests per day.

Q: Does the state still need this additional testing volume now that the winter surge appears to be ending?

A: Along with widespread vaccination, testing availability remains critical to California as the state looks to regain some sense of normal life again. Reliable, timely and cost-effective test results are critical to allowing schools and many businesses to re-open with confidence as the prevalence of COVID-19 continues to decline in California.

Q: Did the laboratory open without appropriate staff training?

A: PerkinElmer has acknowledged that there were a handful of individuals who had science degrees, but not the specific science degrees as required by state requirements. This was quickly identified, and as a result, these individuals were moved to roles that align with their credentials or exited from employment. It is the State's understanding that all individuals who are working in the laboratory and are handling specimens are credentialed and trained.

Q: Is it true that the state has paid PerkinElmer \$1.7 billion?

A: No, while that figure is the maximum amount of the state's contract with PerkinElmer, so far state costs are far below that figure. The state pays a fixed price based on volume and pays an additional variable cost for the number of tests processed. The state collects health insurance information and bills insurers to recoup the cost of testing. The actual amount paid to PerkinElmer to date is \$286.2 million, an amount that will be lowered by insurance reimbursements.

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